



Paul E. Helliker
Director

Department of Pesticide Regulation



Gray Davis
Governor
Winston H. Hickox
Secretary, California
Environmental
Protection Agency

MEMORANDUM

TO: Worker Health and Safety Branch Staff

HSM-01018

FROM: Chuck Andrews, Chief [original signed by C. Andrews]
Worker Health and Safety Branch
(916) 445-4260

DATE: December 21, 2001

SUBJECT: FINALIZING, REVISING, AND RELEASING EXPOSURE ASSESSMENT,
TOXIC AIR CONTAMINANT (TAC), AND MITIGATION DOCUMENTS AS
HEALTH AND SAFETY (HS) REPORTS

This memorandum supercedes Branch policies regarding reviews, revisions, and releases of exposure assessment, toxic air contaminant, and mitigation documents. This memorandum clarifies the procedures on the peer review process for mitigation, TAC and revised exposure assessment documents. Memorandum dated December 22, 2000 (HSM-00006) (C. Andrews to WH&S Staff) is rescinded.

Finalizing Exposure Assessment, TAC and Mitigation HS Reports

The following policy outlines Worker Health and Safety (WH&S) Branch procedures for finalizing exposure assessment, TAC and mitigation documents as HS reports.

1. Staff must obtain an HS report number from support staff for all exposure assessment, TAC and mitigation documents. The book for assigning HS numbers is kept by the Office Assistant.
2. HS reports are considered draft documents during the following processes:
 - (a) Scoping and drafting
 - (b) Internal peer review within the WH&S Branch (i.e., WH&S Branch Peer Review)
 - (c) Internal peer review by other branches (i.e., DPR Peer Review)
 - (d) External peer review by the Office of Environmental Health Hazard Assessment (OEHHA), U.S. Environmental Protection Agency (U.S. EPA), and other agencies or governing bodies.



3. The Author must follow the WH&S Branch Peer Review Process (see attached flow chart) to finalize the document. Keep in mind that you should allow approximately a two-month period for Branch and DPR peer review. The peer review and approval process includes:

(a) **Internal Peer Review by the WH&S Branch (WH&S Branch Peer Review):**

- (1) Submit the document to the Peer Review Manager for Branch peer review. The Author should incorporate the term "Draft" on each page of the document.
- (2) Peer Review Manager assigns two reviewers to comment on the document. Reviewers must provide comments to the Peer Review Manager within three weeks for draft exposure assessment and TAC documents and two weeks for draft mitigation documents. Peer Review Manager reviews the document, compiles all comments and forwards them to the Author.
- (3) Author prepares written responses to the comments and sends the edited document (if any) and response via the Senior Toxicologist to the Peer Review Manager. The Peer Review Manager sends the response to reviewers (if requested). Peer Review Manager reviews the Author's responses to the comments and the edited document. Peer Review Manager sends the document to the Senior Toxicologist and Branch Chief for approval to release for DPR review.

(b) **Internal Peer Review by Other Branches (DPR Peer Review):**

- (1) Draft exposure assessment documents are sent to Medical Toxicology Branch only. Draft TAC documents are sent to Medical Toxicology and Environmental Monitoring Branch. Draft mitigation documents are sent to all branches. The Author should ensure the term "Draft" is typed on each page of the document. DPR reviewers are given three weeks to provide comments to the Peer Review Manager for exposure assessment and TAC documents, and given ten working days to provide comments for draft mitigation documents. Peer Review Manager compiles the comments and forwards them to the Author.
- (2) Author prepares written responses to the comments and sends the edited document (if any) and response via the Senior Toxicologist to the Peer Review Manager. The Peer Review Manager sends the response to persons who commented (if requested). Peer Review Manager reviews the Author's responses to the comments and the modified document.

- (3) If the most current pesticide sales, use and illness data are greater than one year old, the Author should update the information.

(c) External Peer Review (e.g., OEHHA, U. S. EPA, other agencies):

Exposure Assessment Documents

- (1) Forward all requests for processing of final draft exposure assessment documents to the Peer Review Manager. The Author should incorporate the term "Final Draft" on each page of the document. The Peer Review Manager prepares a supplemental tracking sheet with signatures by Lead Author, Senior Toxicologist, and Branch Chief, and forwards the final draft document to the Medical Toxicology Branch.
- (2) The Medical Toxicology Branch assembles the documents into a final draft Risk Characterization Document (RCD) and forwards it to the Registration Branch.
- (3) The Registration Branch sends the final draft RCD (includes final draft exposure assessment document) to OEHHA and U.S. EPA. The Registration Branch may send a final draft RCD (includes final draft exposure assessment document) to the registrant at the same time it is sent to OEHHA and U.S. EPA. Final draft documents sent to the registrant must be made available to the public upon request.
- (4) OEHHA and U.S. EPA are requested to review the document and submit comments within 60 days. The Author shall notify the Peer Review Manager upon receipt of comments. The Author must prepare a response (e.g., memorandum via the Senior Toxicologist to the Branch Chief) addressing the comments submitted by OEHHA and U.S. EPA. The Author sends the comments and responses to the Peer Review Manager and makes any necessary changes to the HS report. The Peer Review Manager will forward a copy of the comments to the Chief of the Medical Toxicology Branch, who will be responsible for sending the response to comments to OEHHA. The response will be included in the RCD file and made available to the public. If no comments were received, the Author must prepare a memorandum via the Senior Toxicologist to the RCD file indicating that no comments were received. Send a memorandum to the Peer Review Manager, who will forward a copy to the Medical Toxicology Branch.
- (5) Occasionally, other institutions or regulatory agencies may peer review a final draft RCD that includes an HS report. The Author must consider these comments before the document is forwarded to the peer review manager for final review and approval. The Author must prepare a response (e.g., memorandum via the Senior Toxicologist to the Branch Chief) addressing the comments submitted. The Author sends the comments and

responses to the Peer Review Manager, who will forward it to the Medical Toxicology Branch. The response will be included in the RCD file available to the public.

- (6) If the most current pesticide sales, use and illness data are greater than one year old, the Author should update the information. The Senior Toxicologist and Peer Review Manager will discuss this with the Author to determine whether the data should be updated.

TAC Documents

- (1) Forward requests for processing a final draft TAC document to the Peer Review Manager. The Author should incorporate the term "Final Draft" on each page of the document. The Peer Review Manager prepares a supplemental tracking sheet with signatures by Lead Author, Senior Toxicologist, and Branch Chief, and forwards the final draft document to the Environmental Monitoring Branch.
- (2) The Environmental Monitoring Branch assembles the documents into a final draft TAC document and sends it to OEHHHA, the Scientific Review Panel and the public for comment.
- (3) The Author must prepare a response (e.g., memorandum via the Senior Toxicologist to the Branch Chief) addressing the comments submitted. The Author will make any necessary changes to the HS report. The Author sends the comments and responses to the Peer Review Manager and makes any necessary changes to the HS report. The Peer Review Manager will forward a copy of the comments to the Environmental Monitoring Branch, who will be responsible for sending the response to comments to OEHHHA. The response will be included in the TAC file and made available to the public. If no comments were received, the Author must prepare a memorandum via the Senior Toxicologist to the TAC file indicating that no comments were received. Send the memorandum to the Peer Review Manager, who will forward a copy to the Environmental Monitoring Branch.
- (4) If the most current pesticide sales, use and illness data are greater than one year old, the Author should update the information. The Senior Toxicologist and Peer Review Manager will discuss this with the Author to determine whether the data should be updated.

(d) Final Review and Approval-Completed Exposure Assessment and TAC Documents:

- (1) The Peer Review Manager will coordinate final approval from the Author, Senior Toxicologist, and Branch Chief. The Peer Review Manager will coordinate final approval

of TAC documents after findings have been approved by the SRP. After the Branch Chief has signed off on the exposure assessment or TAC document, it is considered completed. Remove the term "Final Draft" from each page of the document and send it electronically to the Peer Review Manager. Completed exposure assessment documents are forwarded to the Medical Toxicology Branch for final incorporation into the RCD. Completed TAC documents are forwarded to Environmental Monitoring Branch for final incorporation into the TAC. The final RCD or TAC is forwarded to the Assistant Director for approval. The HS report will be released to the public and posted on the DPR web site after the Assistant Director approves the RCD or TAC.

- (2) There may be situations where the Author will need to modify the HS report after it was signed off by the Branch Chief as "completed", but not approved by the Assistant Director. The Author must follow the procedures under "Revising Completed Exposure Assessment, TAC and Mitigation HS Reports."

(e) Final Review and Approval-Completed Mitigation Documents:

- (1) The Peer Review Manager will coordinate final approval from the Author, Senior Toxicologist, and Branch Chief. After the Branch Chief has signed off on the mitigation document, it will be forwarded to the Assistant Director and Chief Deputy Director for approval. After approval is given, the HS report is completed and can be released to the public and posted on the DPR web site.

Revising Completed Exposure Assessment, TAC and Mitigation HS Reports

The following policy outlines WH&S Branch procedures for revising completed HS reports pertaining to exposure assessment, TAC and mitigation:

1. The Author may need to modify the HS report (exposure assessment and TAC documents only) after it is completed, but prior to receiving RCD or TAC approval (RCD includes completed exposure assessment document) from the Assistant Director.
 - (a) The Author must receive approval in writing from the Senior Toxicologist. The Author should briefly describe in the memorandum the reason(s) for the modification and the portion(s) of the document affected. The Senior Toxicologist must provide a copy of the written approval to the Peer Review Manager.
 - (b) Once approval is received, the Author must obtain an electronic copy of the document from the Peer Review Manager to modify the completed HS report. Before a modified HS report is finalized, the Author and the Peer Review Manager must discuss the changes to determine whether a revision number and WH&S Branch peer

review are necessary. If a revision number is required, follow the procedures outlined in procedure numbers 3-6 below.

- (c) If the most current pesticide sales, use and illness data are greater than one year old, the Author should update the information. The Senior Toxicologist and Peer Review Manager will discuss this with the Author to determine whether the data should be updated.
- 2. After the Branch Chief and the Assistant Director sign off on the HS report, no revisions will be made to the completed exposure assessment, TAC or mitigation documents unless approved in writing by the Senior Toxicologist. HS report revisions include any change in exposure values, data calculations, statistical analyses, new use report data, or the addition of other information or data. An Author requesting a revision to make editorial changes will generally not receive approval. The Senior Toxicologist must provide a copy of the written approval to the Peer Review Manager.
- 3. Once approval is received, the Author must obtain an electronic copy of the document from the Peer Review Manager to revise the completed HS report. The Author should briefly describe in the report the reason(s) for the revision and the portion(s) of the document affected.
- 4. The Author will include a revision number and a revised date on the document. The HS number will remain the same. Leave the original date and any previously revised dates on the document. The document should generally contain the following format:

TITLE
Author
HS-XXXX Date
Revision No X Revised Date.

- 5. Before a revised HS report is finalized, the Author and the Peer Review Manager must discuss the changes to determine whether WH&S Branch peer review is necessary. The Peer Review Manager and Branch Chief will determine whether DPR and External peer review is necessary. If DPR and external peer review is necessary, the Peer Review Manager should immediately notify other branches involved in the peer review process that a completed HS report will be revised.
- 6. The Author and the Peer Review Manager must follow the “final review and approval” procedures in “Finalizing Exposure Assessment, TAC and Mitigation HS Reports.” The previous HS report will be maintained for historical reference.

Release of Completed Exposure Assessment, TAC and Mitigation HS Reports

1. Generally, only completed documents approved by the Assistant Director will be made available to the public. Completed documents approved by the Assistant Director will be in the HS report index (see WH&S Home Page for access) and available on the DPR web site. If you are unsure of the document status, please contact the Peer Review Manager for guidance.
2. The WH&S Branch will maintain on the DPR web site for distribution to the public, the most recent revision of an HS report. Electronic copies of earlier report versions will be maintained for historical purposes. These versions will be available to the public if requested. Staff should check with peer review manager for electronic copies of earlier versions.

If you have any questions, please contact your supervisor.

Attachment

cc: Tobi Jones, Ph.D.
Gary T. Patterson, Ph.D.
Barry Cortez
John Sanders, Ph.D.

WH&S BRANCH PEER REVIEW

Exposure Assessment, Toxic Air Contaminant and Mitigation Documents

